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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,425	02/05/2008	James M. Flory	6304P0021US	3653
⁴¹⁵²⁸ Erickson Law (7590 12/09/201 Group, PC	0	EXAMINER	
	RVILLE ROAD		CHU, KAIYEU K	
WHEATON, IL 60189			ART UNIT	PAPER NUMBER
			3771	
			NOTIFICATION DATE	DELIVERY MODE
			12/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)				
Office Action Comments	10/538,425	FLORY ET AL.				
Office Action Summary	Examiner	Art Unit				
	KAIYEU CHU	3771				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence add	dress			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	I. lely filed the mailing date of this color (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>27 Se</u>	entember 2010					
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•	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
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Disposition of Claims						
4) Claim(s) 1-20 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrav	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-20</u> is/are rejected.	·					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or						
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>27 September 2010</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign	priority under 35 LLS C & 110(a)	(d) or (f)				
	priority under 35 0.5.0. § 119(a)	-(u) or (r).				
·— <u> </u>	<i></i>					
<u> </u>	 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 					
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application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
See the attached detailed Office action for a list of	or the certified copies not receive	u.				
A44-21						
Attachment(s)						
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4)					
3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Uther:						

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DETAILED ACTION

1. This office action is in response to the amendment filed on 09/27/2010. Claims 1-4, 12, 14-16, and 19-20 have been amended, and no claims have been canceled or newly added. As such, claims 1-20 are presently pending.

Claim Objections

2. Claim 14 is objected to because of the following informality: Applicant uses the phrase "beneath said cap and said base" (in line 9). However, it is unclear how the clip can be slid beneath both the cap and the base. Modifying the phrase to - -between said cap and said base- - may make the meaning more clear. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 14-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is no support in the specification or drawings for more than two "first clip-retaining portion[s]" and more than

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two "second clip-retaining portion[s]." The terms "at least one first clip-retaining portion" and "at least one second clip-retaining portion" have enlarged the scope of the invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. **Claims 14 and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Andrew (US Patent No. 3,602,227).

Regarding **claim 14**, Fig. 1 of Andrew teaches an endotracheal tube holder (see Fig. 1) comprising:

- a base (14) having a face-bearing surface (the bottom surface of the endotracheal tube holder shown in Fig. 1);
- a tube holding formation (14, 23) fixed to the base (11) and having two clip-retaining portions (saw-toothed walls 22 and 23), a clip hold down portion (14) providing a cap (dovetail end of projection 14) that overhangs the base and forms a vertical clearance between the base and the cap (see Fig. 1), and a first tube-bearing surface (circular vertical wall area on base 11 connecting saw-toothed walls 22 and 23 and that is intended to contact the tube, as shown in Fig. 2);

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• a clip (2), separate from the base and having two second clip retaining portions (saw-toothed walls 20 and 21), and a second tube bearing surface (the curved vertical wall area adjacent saw-toothed walls 20 and 21), the clip at least partially slidable beneath said cap and said base (as shown in Fig. 2), the second clip-retaining portions engagable with the first clip-retaining portions (see column 2, lines 23-27) when the clip is slid at least partially between the cap and the base in a linear direction to latch the first and second tube bearing surfaces tightly against an endotracheal tube (1) located therebetween (see Fig. 2).

Regarding **claim 19**, Fig. 2 of Andrew teaches a latch element (5, 6) that prevents the first and second clip retaining portions from becoming disengaged. As a result of the latch element, the clamp can only be unfastened by breaking the clamp as shown in Fig. 4 (see column 2, lines 28-30).

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 1, 4-5, 7-8, 10, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez (US Patent No. 6,526,978 B2) in view of Schiefer et al. (US Patent No. 4,118,838) further in view of Wilderman (US Patent No. 4,202,087).

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Regarding **claim 1**, Figs. 1-4 of Dominguez show an endotracheal tube holder (10) having:

a base (17) including a bottom surface bearing against a patient's face;

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- a tube-holding assembly (18, 18A, 18B) having a tube-securing block (18) fixed to the base and two clip-securing blocks (18A, 18B) arranged on opposite sides of the tube-securing block (bottom portion of right angle member 18 that connects sides 18A and 18B) and also fixed to said base; and
- a tube-retaining clip having two legs (19) each engaging with one of the clip-securing blocks (18A, 18B), and each leg being inserted between a respective space between the tube-securing block and the respective clipsecuring block (see Fig. 2).

Dominguez's tube-retaining clip differs from the present invention in that

Dominguez's clip lacks a base end portion. However, Fig. 1 of Schiefer teaches a tubeholding assembly (10) having a tube-securing block (side walls 14) and two clipsecuring blocks (12) arranged on opposite sides of the tube-securing block; a tuberetaining clip (20) having two legs (21) extending from a base end portion (the upper
portion of the clip 20), the legs arranged to be engaged to the clip-securing blocks, each
leg inserted between a respective space (any space that exists between each clipsecuring block and a portion of the tube securing block) between the tube-securing
block and each respective clip-securing block wherein a tube is captured between the
tube-securing block and the base end portion of the clip. Thus, it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to substitute the tube-holding assembly (18, 18A, 18B) and stationary clip (19) of Dominguez with the tube-holding assembly (10) and removable clip (20) as taught by Schiefer so that the clip of the endotracheal tube holder of Dominguez can be easily engaged with the clip securing blocks.

It is noted that the modified Dominguez still fails to teach that the legs straddle the tube-securing block as required. However, Wilderman teaches in Figs. 1-2 a tube-holding assembly (11) and tube-retaining clip (12) similar to that of Schiefer except that the tube holding assembly of Wilderman includes an extended tube-securing block (see groove 18 in Fig. 2) such that the legs (31, 32) of Wilderman's clip straddle the tube-securing block when the clip is engaged to the tube holding assembly. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube-holding assembly of the modified Dominguez with an extended tube-securing block as taught by Wilderman in order to permit a tube to be more properly secured (i.e. a greater surface area of the tube will be contacting the tube-securing block, and thus the tube will be more stably secured).

Regarding **claim 4**, the modified endotracheal tube holder of Dominguez teaches that the clip-securing blocks (Schiefer: 12) each comprise first teeth (Schiefer: 13) on sides of the clip-securing blocks that face toward second each other, and the legs (Schiefer: 21) comprise second teeth (Schiefer: 23) on sides of the legs facing away from each other wherein said first and second teeth are mutually engaged wherein the clip is installed to the base (Schiefer: column 4, lines 18-22).

Regarding **claim 5**, the modified endotracheal tube holder of Dominguez teaches that the first and second teeth are angled in ratchet fashion to allow the clip to be installed by pushing the legs into the spaces while resisting retraction of the legs from engagement to the clip-securing blocks wherein the clip is pulled in an opposite direction (Schiefer: column 2, lines 54-61).

Regarding **claim 7**, the modified endotracheal tube holder of Dominguez teaches that the base (Dominguez: 17) includes arms (Dominguez: each side of chin piece 14) that straddle the patient's mouth extending in a transverse direction to the patient's face and that the tube-securing block (Schiefer: 14) is arranged adjacent to a side of the patient's mouth (see Fig. 1 of Dominguez).

Regarding **claim 8**, the modified endotracheal tube holder of Dominguez teaches a restraining strap (Dominguez: 12, 13) wherein the base includes an attachment (Dominguez: 15A, 16A) for the strap, wherein the strap can encircle the patient's head to hold the base to the patient's face (see Fig. 1 of Dominguez).

Regarding **claim 10**, the modified endotracheal tube holder of Dominguez teaches that the retaining clip is separable from the base when the legs are disengaged from the clip-securing block (see Fig. 1 of Schiefer).

Regarding **claim 12**, the modified endotracheal tube holder of Dominguez teaches that the strap comprises two parallel strap portions (Dominguez: 12, 13), and comprises hook and loop engagable fasteners (Dominguez: 12A, 13A) applied between the top surface of the arms and the restraining strap portions (Dominguez: Fig. 1 shows part of the Velcro engagement occurring between the arm and the strap 13) and the

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strap comprises a base portion (Dominguez: the engagement between the straps 12,13 and the openings 15B, 16B shown in Fig. 2) fixed to the base. For the remaining limitations, refer to the rejection of claim 8 for reasoning.

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Regarding **claim 13**, the modified endotracheal tube holder of Dominguez teaches that the tube-securing block (Schiefer: 14) comprises an overhang position (sides of walls 14 that are adjacent to walls 12) above each space, wherein the overhang portions retain the clip to the base to prevent separation in a direction perpendicular to a top surface of the base.

9. **Claims 2-3** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer further in view of Wilderman as applied to claims 1, 4-5, 7-8, 10, and 12-13 above, and further in view of Hayatdavoudi (US Patent No. 4,823,919).

Regarding **claims 2-3**, the modified Dominguez teaches all of the claimed limitations except that each of the tube-securing block (i.e. first tube-bearing surface) and the base end portion (i.e. second tube-bearing surface) comprises a pair of planar areas of tube-engaging teeth. However, Hayatdavoudi teaches multiple sets of planar areas (see column 3, lines 30-33) of tube-engaging teeth (46) that are used to grip a tube (see column 1, lines 37-41; column 3, lines 16-21). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tube-securing block and base end portion of the modified endotracheal tube holder

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of Dominguez to have multiple planar areas of tube-engaging teeth as taught by Hayatdavoudi in order to more securely hold a tube in position.

10. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer further in view of Wilderman as applied to claims 1, 4-5, 7-8, 10, and 12-13 above, and further in view of Rosenbeck (US Patent No. 3,940,823).

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Regarding **claim 6**, the modified Dominguez teaches all of the claimed limitations except that the legs can be squeezed together to release the first teeth from the second teeth to remove the clip from the tube-holding assembly. Instead, Schiefer teaches that the clip may be removed by using a tool such as a screwdriver to force the clip-retaining blocks to disengage from the legs of the clip (see column 4, lines 26-29). However, Rosenbeck teaches a clip with members (74, 76) that must be squeezed together in order to release the clip from the structure it is engaged to (see column 4, lines 52-57). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the legs of the modified endotracheal tube holder of Dominguez to be able to be squeezed together (while also making sure that the tube holding block doesn't hinder the squeezing) like the members on the clip of Rosenbeck, as doing so would allow the clip of Dominguez to be much more easily removed than by using its current method of using a screwdriver.

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11. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer further in view of Wilderman as applied to claims 1, 4-5, 7-8, 10, and 12-13 above, and further in view of Islava (US Patent No. 5,829,430).

Regarding claims 9, the modified Dominguez teaches all of the claimed limitations except that the base comprises a bite block that extends below said bottom surface into the patient's mouth to prevent closing together of the patient's upper and lower teeth. However, Islava teaches an endotracheal tube holder (10) with a bite block (45) that extends below said bottom surface of a base (18) of the endotracheal tube holder into a patient's mouth to prevent closing together of the patient's upper and lower teeth. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the base of the modified endotracheal tube holder of Dominguez with a bite block that extends into a patient's mouth as taught by Islava, as doing so would help the modified endotracheal tube holder of Dominguez secure an endotracheal tube.

12. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer further in view of Wilderman as applied to claims 1, 4-5, 7-8, 10, and 12-13 above, and further in view of Wing et al. (US Patent No. 6,409,220 B1).

Regarding **claim 11**, the modified Dominguez teaches all of the claimed limitations except a tether connecting the base and the clip. However, Fig. 1 of Wing teaches a tether (60) connecting a body portion (20) to a cap portion (80). Thus, it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the base and the clip of the modified endotracheal tube holder of Dominguez to have a tether connecting the two elements together as taught by Wing, as doing so would help prevent loss or misplacement of either the clip or the base.

13. Claims 14-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez (US Patent No. 6,526,978 B2) in view of Schiefer et al. (US Patent No. 4,118,838).

Regarding **claim 14**, Figs. 1-4 of Dominguez show an endotracheal tube holder (10) having:

- a base (17) including a bottom surface bearing against a patient's face;
- a tube-holding formation (18, 18A, 18B) having a tube-securing block (18) fixed to the base and two clip-securing blocks (i.e. first clip-retaining portions) (18A, 18B) arranged on opposite sides of the tube-securing block (bottom portion of right angle member 18 that connects sides 18A and 18B) and a first tube-bearing surface (surface proximate the tube);
- a clip (19) having a second clip-retaining member (legs of clip 19) and a second tube-bearing surface (where the legs of clip 19 retain the tube).

It is noted that Dominguez does not teach a clip hold down portion and the second clip-retaining member being engagable with the first clip-retaining member when the clip is pushed onto the base in a linear direction to latch the first and second tube-

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bearing surfaces tightly against a tube located. However, Fig. 1 of Schiefer teaches a tube-holding formation (10) having a two clip-securing blocks (12), a clip hold down portion (one side wall 14) providing a cap (top edge of the side wall 14 where the reference 14 points to in Fig. 1) that overhangs a base (other side wall 14) and forms a vertical clearance between the base and the cap, and a first tube-bearing surface (circular wall area on first side wall 14); and a clip (20) having a second clip-retaining portion (21), and a second tube-bearing surface (where the clip 20 retains a tube), the clip at least partially slidable beneath the cap and the base, the second clip-retaining portion engagable with the first clip-retaining portion when the clip is slid at least partially between the cap and the base in a linear direction to latch the first and second tube-bearing surfaces tightly against a tube located therebetween (see column 4, lines 18-22). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the first clip-retaining member and the clip of Dominguez with the first clip-retaining member and engagable clip as taught by Schiefer (this combination also results in extending the base of Dominguez to include the other side wall 14 of Schiefer) so that the clip of the endotracheal tube holder of Dominguez can be easily engaged with the first clip-retaining member.

Regarding **claim 15**, the modified endotracheal tube holder of Dominguez teaches that the first clip-retaining portion comprises two clip-retaining blocks (Schiefer: 12) arranged on opposite sides of, and spaced from, the first tube-bearing surface, and the second clip-retaining portion comprises two legs (Schiefer: 21), each leg engagable to a respective one clip-retaining block (Schiefer: column 3, line 64 – column 4, line 3).

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Regarding **claim 17**, the modified endotracheal tube holder of Dominguez teaches that the base comprises spaced apart arms (Dominguez: each side of chin piece 14) for bearing on the patient's face, straddling the patient's mouth, and a base portion (Dominguez: part of base 17 that connects arm flaps of chin piece 14 together) connecting the arms and carrying the first tube-bearing surface, the first tube-bearing surface arranged to be located at a corner of the patient's mouth.

14. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer as applied to claims 14-15 and 17 above, and further in view of Hayatdavoudi (US Patent No. 4,823,919).

Regarding **claim 16**, the modified Dominguez teaches all of the claimed limitations except that each of the first tube-bearing surface and the second tube-bearing surface comprise a pair of planar areas of tube-engaging teeth. However, Hayatdavoudi teaches multiple sets of planar areas (see column 3, lines 30-33) of tube-engaging teeth (46) that are used to grip a tube (see column 1, lines 37-41; column 3, lines 16-21). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tube-securing block and base end portion of the modified endotracheal tube holder of Dominguez to have multiple planar areas of tube-engaging teeth as taught by Hayatdavoudi in order to more securely hold a tube in position.

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15. **Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer as applied to claims 14-15 and 17 above, and further in view of Wing et al. (US Patent No. 6,409,220 B1).

Regarding **claim 18**, the modified Dominguez teaches all of the claimed limitations except a tether connecting the base and the clip. However, Fig. 1 of Wing teaches a tether (60) connecting a body portion (20) to a cap portion (80). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the base and the clip of the modified endotracheal tube holder of Dominguez to have a tether connecting the two elements together as taught by Wing, as doing so would help prevent loss or misplacement of either the clip or the base.

16. **Claims 19-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dominguez in view of Schiefer as applied to claims 14-15 and 17 above, and further in view of Young, Jr., et al (US Patent No. 2,534,690).

Regarding **claims 19 and 20**, the modified Dominguez teaches all of the claimed limitations except for a latch element. However, Figs. 1-2 of Young teaches a first clip-retaining member (10) and a clip (40) having at least one second clip-retaining member (48, 49), and a second tube-bearing surface, the second clip-retaining member engagable with the first clip-retaining member when the clip is pushed onto the base in a linear direction to latch the first and second tube-bearing surfaces tightly against a tube located therebetween (see column 2, lines 42-45); the first clip-retaining member comprises two clip-retaining blocks (14, 15) arranged on opposite sides of, and spaced

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from, the first tube-bearing surface, and the second clip-retaining member comprises two legs (48, 49), each leg engagable to a respective one clip-retaining block (see column 4, lines 11-15); and at least one latch element (44, 45) for engaging with notches (16, 17) and that is manually movable and arranged to brace between the first leg (48) and the second leg (49) to prevent disengagement of the legs and the clip-retaining blocks. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the first and second clip-retaining portions of the modified Dominguez with notches and latches, respectively, as taught by Young, in order to provide the modified Dominguez with an additional method of ensuring connection between the first and second clip-retaining portions.

Response to Arguments

- 17. Applicant's arguments filed 9/27/2010 have been fully considered but they are not persuasive.
- 18. In the first paragraph on page 11 of the Remarks, Applicant asserts that the vertical engagement of the two pieces in the Andrew reference occurs below the upper surface of the holder and can not be as easily visually verified and assembled during an emergency as compared to the present invention set forth in claim 14. However, this alleged distinction between Andrews and the present invention is not set forth in the claim.
- 19. Applicant's remaining arguments with respect to claims 1-20 have been considered but are moot in view of the new grounds of rejection.

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Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAIYEU CHU whose telephone number is (571)270-5376. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAIYEU CHU/ Examiner, Art Unit 3771 12/2/2010

/Edward K. Look/ Supervisory Patent Examiner, Art Unit 3745